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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Robert Lawton

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20306

7590

09/04/2002

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EXAMINER

FORD, VANESSA L

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 09/04/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/765,739

Applicant(s)

LAWTON ET AL.

Examiner

Vanessa L. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 and 25-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12 and 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### FINAL ACTION

1. This Office Action is responsive to Applicant's response filed June 27, 2002, claims 22-24 has been amended.
2. In view of Applicant's amendment the objection to claims 22-24 are withdrawn.
3. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

### ***Rejections Maintained***

4. The rejection of claims 21-24 under 35 U.S.C. 112, first paragraph maintained for <sup>JS</sup> the reasons set forth in pages 2-4, paragraph 3 of the previous Office Action.

The rejection was on the grounds that Claims 21-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. *This is a written description rejection.*

The specification broadly describes as a part of the invention polypeptides consisting of the polypeptides SEQ ID Nos: 1-7. The specification states that "variants in which amino acids of the polypeptides of the invention are substituted, deleted or added in any combination are contemplated by the invention". The specification also states "that naturally occurring variants and non-naturally occurring variants are include in the invention and may be produced by mutagenesis techniques or by direct synthesis" (page 7). Applicant has broadly described the invention as embracing any substitution, insertion or deletion change of amino acids throughout the length of the polypeptide sequence. Variants SEQ ID Nos: 1-7 correspond to sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a variant degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 U.S.C. 112, first, paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date

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sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NOs:1-7, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptide regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Therefore, only SEQ ID NO: 1-7 but not the full breadth of the claim (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant urges that one skilled in the art would recognize that the Applicants were in possession of an isolated polypeptide selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID No:3, SEQ ID No:4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO:7 and variants thereof. Applicant urges that the specification teaches polypeptides that do not comprise 100% identity to a polypeptide sequence shown in SEQ ID Nos:1-7 are considered "variants" and the invention provides polypeptides with 85%-99% identity to the sequences shown in SEQ ID Nos:1-7. Applicant urges that the specification defines that meaning of "identity" and explains that sequences are aligned for identity calculations using a mathematical algorithm. Applicant further urges that one skilled in the art would recognize that the Applicants were in possession of polypeptides having a certain percentage sequence identity to SEQ ID Nos:1-7 and also specifically bind an anti-*Ehrlichia* antibody.

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Applicant's arguments filed June 27, 2002 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing <sup>on</sup> ~~of~~ the record to *show* that the specification is enabled for the full scope of the claims and therefore does not meet the written description requirement as set forth in 35 U.S.C. 112, first paragraph. Applicant has not shown enablement for variants of SEQ ID Nos 1-7. The specification discloses only species SEQ ID NOs: 1-7 within the genus of the claimed invention. The specification proposes to discover other members of the genus by using a sequence comparison algorithm (pages 6-7). The specification also states "that naturally occurring variants and non-naturally occurring variants are include in the invention and may be produced by mutagenesis techniques or by direct synthesis" (page 7). There is no description of the mutational sites that exist in nature. The specification discloses only SEQ ID NO:1-7 which corresponds to an isolated polypeptide of *Enrlichia*. While use of BLAST and other sequence comparison tools are known, it is not routine in the art to screen for multiple substitutions or multiple modifications of other types and the positions within the polypeptide's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any protein and the result of such modifications is unpredictable based on the instant disclosure. However, the claims are directed to a device containing amino acid sequences that are measured using a sequence comparison algorithm and binds anti-*Ehrlichia* antibodies which encompasses sequences from other species, mutated sequences, splice variants, sequences that have a recited degree of identity (similarity, homology), and so forth. The general knowledge of the art concerning species does not

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provide any indication of how the structure of a limited number of other species is representative of unknown species. The nature of the species within a genus are variant structures.

5. The rejection of claims 21-24 under 35 U.S.C. 112, first paragraph<sup>15</sup> maintained for claims 21-24 for the reasons set forth in pages 4-6, paragraph 4 of the previous Office Action.

The rejection was on the grounds that Claims 21-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-7 are directed to isolated polypeptides selected from the groups consisting of SEQ ID NOs: 1-7 and variants thereof.

The specification is enabling only for the polypeptides of SEQ ID NOs:1-7 as disclosed in the specification. The specification states that "variants in which amino acids of the polypeptides of the invention are substituted, deleted or added in any combination are contemplated by the invention". The specification also states "that naturally occurring variants and non-naturally occurring variants are include in the invention and may be produced by mutagenesis techniques or by direct synthesis" (page 7). The specification teaches that there are many tolerable and conservative amino acid substitutions which can be made that are not critical to protein function (pages 7-9). There is no guidance provided as to which amino acids can be added, deleted or substituted and the polypeptide would retain its biological function. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claims and the claims broadly encompass a significant number of inoperative species. Since the amino acid sequence of the polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar activity/utility requires a knowledge with regard to which amino acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved (i.e. expected intolerant to modification) and detailed knowledge of the ways in which the polypeptide's structure relates to function. However, the problem of the prediction of polypeptide structure from mere sequence data of a single polypeptide and in turn utilizing predicted structural determinations to ascertain functional aspects of the polypeptide and finally what changes can be tolerated with respect thereto is extremely complex and outside of the realm of routine experimentation.

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While recombinant and mutagenesis techniques are known, it is not routine in the art to screen multiple substitutions or multiple modifications of other types and the positions within the polypeptide's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any polypeptide and the result of such modifications is unpredictable based on the instant disclosure. One skilled in the art would expect any tolerance to modifications, e.g., multiple substitutions. The sequence of some polypeptides is highly conserved and one skilled in the art would not expect tolerance to any amino acid modification in such polypeptides.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to selecting other antigens having claimed functional features, 3) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level). One of skill in the art would require guidance, in order to make or use polypeptides that are variants of SEQ ID NOs: 1-7 in a manner reasonable in correlation with the scope of the claims. Without proper guidance, the experimentation is undue.

Applicant urges that the specification teaches that a variant of polypeptide of the invention has 85%-99% identity to a polypeptide sequence shown in SEQ ID Nos:1-7 and specifically binds to anti-*Ehrlichia* antibody. Applicant urges that one skilled in the art can clearly make a polypeptide once the sequence was designed. Applicant urges that even though it could conceivably take a considerable amount of experimentation to design and make a variant polypeptide of the invention, such design and manufacture requires only routine experimentation that is well-known and understood to one skilled in the art. Applicant further urges that the specification provides direction to guide one

of skill in the art to the experimentation necessary to design, make and screen a variant polypeptide of the invention.

Applicant's arguments filed June 27, 2002 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant has not shown enablement for variants of SEQ ID Nos:1-7. The specification discloses only species SEQ ID NOs: 1-7 within the genus of the claimed invention. The specification proposes to discover other members of the genus by using a sequence comparison algorithm (pages 6-7). The specification also states "that naturally occurring variants and non-naturally occurring variants are include in the invention and may be produced by mutagenesis techniques or by direct synthesis" (page 7). There is no description of the mutational sites that exist in nature. The specification discloses only SEQ ID Nos:1-7 which corresponds to an isolated protein of *Enrlichia*. While sequence algorithm techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications of other types and the positions within the protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any protein and the result of such modifications is unpredictable based on the instant disclosure. Therefore, the specification fails to provide guidance as to which amino acids can be changed and the polypeptides still retain their claimed biological function. The nature of the species within a genus are variant structures. In the present state of the art, the structure of a limited number of species does not provide guidance to the structure of others and is insufficient to support the claimed invention.



4. The rejection of claims 21-24 under 35 U.S.C. 102(a) is maintained for claims 21-24 for the reasons set forth in pages 7-8, paragraph 5 of the previous Office Action.

The rejection was on the grounds that Waner et al teach the use of a device (i.e. a clinic ELISA test kit). Waner et al teach that *Ehrlichia canis* IgG antibody titers of serum samples were determined by using a commercial ELISA test kit containing plastic combs sensitized with *E. canis* antigen. Waner et al teach that the sera to be tested was incubated with the comb (containing antigen dots). Waner et al teach that after washing away unbound antibodies the comb were allowed to react with goat anti-dog IgG alkaline phosphatase conjugate. Waner et al teach that bound antibodies were detected with a precipitating chromogen, 5-bromo-4chloro-3-indolyl phosphate and nitro-blue tetrazolium. The polypeptide sequence contained on the plastic comb (i.e. device) would be inherent in the teachings of the prior art. It is well known in the art to include instructions for using polypeptides for the identification of an *Ehrlichia* infection in a mammal in a diagnostic kit. The instructions for performing various immunoassays (i.e. western blot, reversible flow chromatographic binding assay, enzyme linked immunosorbent assay or indirect immunofluorescence assay) are well known in the art. The device of Waner, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's device with the device of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the device of the prior art does not possess the same material structural and functional characteristics of the claimed device). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that Waner et al do not teach or suggest the use of any kind of *E. chaffeensis* polypeptide in a device. Applicant urges that SEQ ID Nos:3-7 of the present invention are *E. chaffeensis* polypeptides and therefore cannot be anticipated by Waner et al. Applicant urges that Waner et al do not teach or suggest the use of distinct *E. canis* polypeptides as shown in SEQ ID Nos:1-2. Applicant urges that Waner et al teach an antigen purified from *E. canis* infected cells in disclosed assays and Waner et al do not teach, suggest or inherently disclose the specific individual polypeptides shown in SEQ ID Nos:1-2. Applicant urges that Waner et al do not identify the

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polypeptide fragments to be ~~use~~ of any particular diagnostic use. Applicant urges that there is no teaching in Waner et al directly or inherently that would direct one of skill in the art to the particular defined sequences of SEQ Nos:1-2 for any reason. Applicant urges that Waner et al do not teach or suggest the SEQ ID Nos:1-2 are sequences that would be useful as individual peptides apart from the entire *E. canis* infected cells or proteins and Waner et al provides no recognition or suggestion that the distinct polypeptides shown in SEQ ID Nos:1-2 or any other polypeptide fragments would be of diagnostic use.

Applicant's arguments filed June 27, 2002 have been fully considered but they are not persuasive. Applicant appears to be arguing limitations that are not in the claims. The claims are drawn to a device containing one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID Nos:1-7 and variants thereof. It is the Examiner's position that there is nothing on the record to show that the teaching of the prior art do not anticipate the claimed invention. Waner et al teach the use of a device (i.e. a clinic ELISA test kit). Waner et al teach that *Ehrlichia canis* IgG antibody titers of serum samples were determined by using a commercial ELISA test kit containing plastic combs sensitized with *E. canis* antigen. The polypeptide sequence contained on the plastic comb (i.e. device) would be inherent in the teachings of the prior art. It is well known in the art to include instructions for using polypeptides for the identification of an *Ehrlichia* infection in a mammal in a diagnostic kit. It should be noted that the claimed device contains polypeptides that detect *Ehrlichia* infection wherein the infection is caused by *Ehrlichia canis* or *Enrlichia chaffeensis* and that the polypeptides

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detect the presence of *Ehrlichia* antibodies not that the claimed polypeptides are from *Enrlichia*. Applicant has provided no side-by-side comparison to show: that the device of the prior art differs from the device of the claimed invention.

5. The rejection of claims 21-24 under 35 U.S.C. 102(b)<sup>15</sup> maintained for claims 21-24 for the reasons set forth in pages 8-9, paragraph 6 of the previous Office Action.

The rejection was on the grounds that Cadman et al teach a device (i.e. a cross dot blot apparatus), nitrocellulose paper was coated with *E. canis* antigen. Cadman et al teach that 0.7 µg of protein in TBS was use per dot. Cadman et al teach that test sera was incubated with the antigen (dots on nitrocellulose paper). Cadman et al teach that the bound antibody was detected with peroxidase-labeled goat anti-dog IgG and 4-chloronaphthol. The polypeptide sequence contained on the nitrocellulose membrane (i.e. device) would be inherent in the teachings of the prior art. It is well known in the art to include instructions for using polypeptides for the identification of an *Ehrlichia* infection in a mammal in a diagnostic kit. The instructions for performing various immunoassays (i.e. western blot, reversible flow chromatographic binding assay, enzyme linked immunosorbent assay or indirect immunofluorescence assay) are well known in the art. The device of Cadman, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's device with the device of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the device of the prior art does not possess the same material structural and functional characteristics of the claimed device). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Applicant urges that Cadman et al do not teach or suggest the use of any kind of *E. chaffeensis* polypeptide in a device. Applicant urges that SEQ ID Nos:3-7 of the present invention are *E. chaffeensis* polypeptides and therefore cannot be anticipated by Cadman et al. Applicant urges that Cadman et al do not teach or suggest the use of distinct *E. canis* polypeptides as shown in SEQ ID Nos:1-2. Applicant urges that Cadman et al teach an antigen purified from *E. canis* infected cells in disclosed assays

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and Cadman et al do not teach, suggest or inherently disclose the specific individual polypeptides shown in SEQ ID Nos:1-2. Applicant urges that Cadman et al do not identify the polypeptide fragments to be use of any particular diagnostic use. Applicant urges that there is no teaching in Cadman et al directly or inherently that would direct one of skill in the art to the particular defined sequences of SEQ Nos:1-2 for any reason. Applicant urges that Cadman et al do not teach or suggest the SEQ ID Nos:1-2 are sequences that would be useful as individual peptides apart from the entire *E. canis* infected cells or proteins and Cadman et al provides no recognition or suggestion that the distinct polypeptides shown in SEQ ID Nos:1-2 or any other polypeptide fragments would be of diagnostic use.

Applicant's arguments filed June 27, 2002 have been fully considered but they are not persuasive. Applicant appears to be arguing limitations that are not in the claims. The claims are drawn to a device containing one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID Nos:1-7 and variants thereof. It is the Examiner's position that there is nothing on the record to show that the teaching of the prior art do not anticipate the claimed invention. Cadman et al teach a device (i.e. a cross dot blot apparatus), nitrocellulose paper was coated with *E. canis* antigen. The polypeptide sequence contained on the nitrocellulose membrane (i.e. device) would be inherent in the teachings of the prior art. It is well known in the art to include instructions for using polypeptides for the identification of an *Ehrlichia* infection in a mammal in a diagnostic kit. It should be noted that the claimed device contains polypeptides that detect *Ehrlichia* infection wherein the infection is caused by *Ehrlichia*

*canis* or *Ehrlichia chaffeensis* and that the polypeptides detect the presence of *Ehrlichia* antibodies not that the claimed polypeptides are from *Ehrlichia canis* or *Ehrlichia chaffeensis*. Applicant has provided no side-by-side comparison to show: that the device of the prior art differs from the device of the claimed invention.

5. The rejection of claims 21-24 under 35 U.S.C. 102(b)<sup>is</sup> maintained for claims 21-24 for the reasons set forth in pages 9-10, paragraph 7 of the previous Office Action.

Applicant urges that Zhi et al do not teach or suggest the use of any kind of *E. chaffeensis* polypeptide in a device. Applicant urges that Zhi et al teach assays for the detection of Human Granulocytic Ehrlichiosis Agent (HEG). Applicant urges that Zhi et al do not teach or suggest the use of distinct *E. canis* and *E. chaffeensis* polypeptides as shown in SEQ ID Nos:1-7. Applicant urges that Zhi et al teach an antigen purified from HEG and rP44 (a 35kDA fusion protein) in disclosed assays. Applicant urges that Zhi et al do not identify the polypeptide fragments to be use of any particular diagnostic use. Applicant urges that there is no teaching in Zhi et al directly or inherently that would direct one of skill in the art to the particular defined sequences of SEQ Nos:1-7. Applicant urges that Cadman et al do not teach or suggest the SEQ ID Nos:1-7 are sequences that would be useful as individual peptides apart from the entire He organisms or HEG rP44 and Cadman et al provides no recognition or suggestion that the distinct polypeptides shown in SEQ ID Nos:1-7 or any other polypeptide fragments would be of diagnostic use.

Applicant's arguments filed June 27, 2002 have been fully considered but they are not persuasive. Applicant appears to be arguing limitations that are not in the claims. The claims are drawn to a device containing one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID Nos:1-7 and variants thereof. It is the Examiner's position that there is nothing on the record to show that the teaching of the prior art do not anticipate the claimed invention. Zhi et al teach a device (i.e. dot blot apparatus comprising a nitrocellulose membrane). Zhi et al further teach that the peroxidase-positive band were detected by immersing the nitrocellulose membrane in a developing solution indicating *Ehrlichia* infection (page 1668, 1<sup>st</sup> column). The polypeptide sequence contained on the nitrocellulose membrane (i.e. device) would be inherent in the teachings of the prior art. It is well known in the art to include instructions for using polypeptides for the identification of an *Ehrlichia* infection in a mammal in a diagnostic kit. It is well known in the art to include instructions for using polypeptides for the identification of an *Ehrlichia* infection in a mammal in a diagnostic kit. It should be noted that the claimed device contains polypeptides that detect *Ehrlichia* infection wherein the infection is caused by *Ehrlichia canis* or *Enrlichia chaffeensis* and that the polypeptides detect the presence of *Ehrlichia* antibodies not that the claimed polypeptides are from *Ehrlichia canis* or *Ehrlichia chaffeensis*. Applicant has provided no side-by-side comparison to show: that the device of the prior art differs from the device of the claimed invention.

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9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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10. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

  
Vanessa L. Ford  
Biotechnology Patent Examiner  
August 27, 2002

  
LYNETTE R. P. SMITH  
SUPERVISORY PATENT EXAMINER  
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